K012628

OCT 2 6 2001

SECTION 7

## SUMMARY OF SAFETY AND EFFECTIVENESS

**510(k) Summary of Safety and Effectiveness**

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

**Modified Device Name:** GYNECARE Tension Free Vaginal Tape (TVT) System with Accessories
- TVT Reusable Introducer
- TVT Reusable Rigid Catheter Guide
- TVT-AA Abdominal Guides and Couplers

**Predicate Device Name:** GYNECARE Tension Free Vaginal Tape (TVT) System with Accessories
- TVT Reusable Introducer
- TVT Reusable Rigid Catheter Guide

Cook OB/GYN Stamey Needle

510(K) SUMMARY

**Device Description**

The Tension Free Vaginal Tape (TVT) System is comprised of three components; the device (TVT device) and its accessories (TVT Introducer and TVT Rigid Catheter Guide and TVT Abdominal Guides and Couplers). Each is available separately for use at the surgical site. The TVT device is composed of unpigmented or blue pigmented PROLENE polypropylene mesh (tape). The mesh is covered with a polyethylene sheath with a slit in the middle. Both the mesh and sheath are attached to two (2) stainless steel needles. The TVT Introducer (accessory) is made of stainless steel. It is composed of three (3) parts; handle, threaded shaft and rubber O-ring. The introducer functions to facilitate passage of the TVT device from the vagina to the abdominal skin. The TVT Rigid Catheter Guide is made of stainless steel and used to add rigidity to the Foley Catheter during the surgical procedure. The TVT AA (Accessory) Abdominal Guide is made of stainless steel and the couplers are made from polypropylene.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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|---|---|
| **Intended Use** | The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI). |
| **Indications Statement** | The TVT device is intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI) for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer, Rigid Catheter Guide and TVT abdominal Guides and Couplers accessories are intended to facilitate placement of the TVT device. |
| **Technological Characteristics** | Technologically both the modified TVT Blue device and the currently marketed predicate device are the same. The TVT-AA Abdominal Guides and Couplers is an accessory that may be used with the modified device or the modified device to facilitate an abdominal approach for the placement of the TVT mesh. |
| **Performance Data** | Results of bench testing and preclinical evaluations were used to show that the TVT System functioned as clinically intended and have the same product properties. |
| **Conclusions** | Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act. |
| **Contact** | Gregory R. Jones<br>Director of Regulatory Affairs & Quality Assurance<br>GYNECARE<br>A Division of ETHICON, Inc.<br>Rt. #22 West<br>Somerville, NJ 08876-0151 |
| **Date** | August 9, 2001 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Gregory R. Jones
Director of Regulatory Affairs
and Quality Assurance
Gynecare
Division of Ethicon , Inc.
P.O. Box 151
Somerville, New Jersey 08876

Re: K012628
Trade/Device Name: GYNECARE Tension-Free Vaginal Tape (TVT) Blue System
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 9, 2001
Received: August 13, 2001

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, RS

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATION FOR USE**

**510(k) Number (if known):** K012628

**Device Name:** Tension Free Vaginal Tape (TVT) Blue System

**Indications for Use:** The TVT device is intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI) for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer, Rigid Catheter Guide and TVT Abdominal Guides and Couplers are accessories intended to facilitate placement of the TVT device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off) (~~Optional~~ Format 1-2-9G)
Division of General, Restorative and Neurological Devices